

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9095

Bartle, J.

June 25, 2013

Sharon S. Vang ("Ms. Vang" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Harold D. Vang, Ms. Vang's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2003, claimant submitted a Green Form to the Trust signed by her attesting physician, Brent T. McLaurin, M.D., F.A.C.C., F.S.C.A.I. Based on an echocardiogram dated September 9, 2002, Dr. McLaurin attested in Part II of Ms. Vang's Green Form that claimant had valvular repair or replacement surgery and required a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

initial surgery.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level IV benefits in the amount of \$1,042,584.⁵

Dr. McLaurin also attested in claimant's Green Form that Ms. Vang did not have mitral annular calcification or chordae tendineae rupture. Under the Settlement Agreement, the presence of mitral annular calcification and/or chordae tendineae rupture requires the payment of reduced Matrix Benefits. See Settlement Agreement §§ IV.B.2.d.(2)(c)ii)c)-d). As the Trust does not contest Ms. Vang's entitlement to Level IV benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In July, 2004, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. McLaurin's finding that claimant did not have mitral annular calcification. At that time, Dr. Oliner concluded, however, that there was a reasonable medical basis for

4. Dr. McLaurin also attested that Ms. Vang suffered from a reduced ejection fraction in the range of 50% to 60% and New York Heart Association Functional Class III symptoms and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she "had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery." See Settlement Agreement § IV.B.2.c.(4)(g).

Dr. McLaurin's finding that claimant did not have chordae tendineae rupture.

Based on Dr. Oliner's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Vang was entitled only to Matrix B-1, Level IV benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶

The Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Oliner submitted a declaration in which he concluded that there was a reasonable medical basis for Dr. McLaurin's representation that claimant did not have mitral annular calcification. Dr. Oliner, however, determined that there was no reasonable medical basis for Dr. McLaurin's representation that claimant did not have chordae tendineae rupture. Dr. Oliner explained:

7. During my audit of the claim in August 2004, I observed that Claimant had severe mitral regurgitation and mild mitral annular calcification based on the January 16, 1997 echocardiogram. I did not observe chordae tendinae [sic] rupture or mitral valve prolapse on the January 16, 1997 echocardiogram performed four weeks prior to Claimant's mitral valve replacement. I did

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Vang's claim.

however note, and commented in my report, that the surgeon who performed Claimant's mitral valve replacement on February 10, 1997, observed "prolapse of the mitral valve anterior leaflet, elongation of the chordae, and ruptured chordae" during the surgery (See Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue ("Oliner Report").)

8. The February 10, 1997 operative report states, "[e]xamination revealed a mildly dilated mitral annulus with prolapse of the anterior mitral leaflet and severe elongation of the chordae with a few small ruptured chordae." (See February 10, 1997 operative report.) Although I saw no echocardiographic evidence of chordae tendinae [sic] rupture or mitral valve prolapse on the echocardiogram, the surgeon who performed the mitral valve replacement was in the best position to examine Claimant's mitral valve leaflets and chordae tendinae [sic]. Based upon the explicit findings in the operative report, I conclude that Claimant had mitral valve prolapse and chordae tendinae [sic] rupture.

9. In reaching my original findings at audit, I considered only the echocardiographic evidence. Based on the entirety of the medical record, I now conclude that there is no reasonable medical basis for the Attesting Physician's failure to find ... chordae tendinae [sic] rupture.

....

11. Accordingly, I hereby amend the record to reflect my findings that there is a reasonable medical basis for the Attesting Physician's failure to find mitral annular calcification and there is no reasonable medical basis for the Attesting Physician's failure to find mitral valve prolapse and chordae tendinae [sic] rupture.

Based on Dr. Oliner's conclusion that claimant had chordae tendineae rupture, the Trust issued an amended post-audit determination, again determining that Ms. Vang was entitled only

to Matrix B-1, Level IV benefits. Claimant also contested this adverse determination. In contest, claimant submitted the statements of Dr. McLaurin, Arthur Levene, M.D., and Robin Schroeder, R.D.C.S., a cardiac sonographer. Dr. McLaurin and Dr. Levene each stated that they reviewed claimant's medical records, including her January 16, 1997 echocardiogram and February 10, 1997 operative report, and concluded that Ms. Vang did not have chordae tendineae rupture prior to her mitral valve surgery. Dr. McLaurin and Dr. Levene also opined that the chordae tendineae rupture noted in Ms. Vang's operative report was a result of the surgical proceeding and not because of a condition of Ms. Vang. Ms. Schroeder also reviewed claimant's January 16, 1997 echocardiogram and concluded that there was no evidence of chordae tendineae rupture. Claimant argued that Dr. Oliner's original audit finding confirmed that there was no evidence of chordae tendineae rupture on Ms. Vang's January 16, 1997 echocardiogram.

The Trust then forwarded the claim for a third review by the auditing cardiologist. Dr. Oliner submitted another declaration in which he confirmed his finding that there was no reasonable medical basis for the attesting physician's conclusion that claimant did not have chordae tendineae rupture. Specifically, Dr. Oliner explained:

9. Claimant's surgeon performed a mitral valve replacement on February 10, 1997. The surgeon's operative report describes what he saw when he first visualized Claimant's

mitral valve and chords. Specifically, Claimant's surgeon states:

FINDINGS

Examination revealed a mildly dilated mitral annulus with prolapse of the anterior mitral leaflet and severe elongation of the chordae with a few small ruptured chordae. Attempt was made to replace these with Gore-Tex suture, but the exposure was very difficult on this obese lady and [I] was not happy with the result. I felt that her best option was mitral valve replacement with chordal preservation.

Claimant's severely elongated chordae and ruptured chordae as described in the operative report are consistent with preexisting chordal disease. There is no doubt that the surgeon's eyes are far more sensitive to elongated and ruptured chords than an echocardiogram. The fact that ruptured chordae tendonae [sic] are not visualized on an [echocardiogram] does not rule out their presence. Various factors, including the technical quality of the [echocardiogram], the size, thickness and location of the ruptured chordae, and the degree of chordal rupture, can and often do prevent ruptured chordae from being visualized on an [echocardiogram].

Claimant's Attesting Physician and expert assert in Claimant's Contest that Claimant's chordae were intact prior to the surgery and that the chordae tendineae ruptured during the surgical procedure. Claimant's experts assert that the difficulty of the surgery caused the chords to rupture. The surgeon's "FINDINGS," however, describe what he found at the onset of the procedure, not what he visualized after he began the difficult process of attempting to repair the valve. Additionally, the surgeon himself does not suggest or state that any chordae ruptured during the surgery. The rupture of

the chordae during surgery is highly unlikely and extremely uncommon.

Moreover, Claimant's experts' hypothesis that the chords ruptured during surgery does not explain the severe elongation of the chords - a characteristic consistent with preexisting chordal disease.

10. Accordingly, I hereby affirm my findings as stated in my December 6, 2004 Declaration that (a) Claimant has chordae tendineae rupture and (b) there is no reasonable medical basis for the Attesting Physician's finding that Claimant does not have chordae tendineae rupture.

The Trust then issued a final post-audit determination, again determining that Ms. Vang was entitled only to Matrix B-1, Level IV benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Vang's claim should be paid. On October 26, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5811 (Oct. 26, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 10, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Vang did not have chordae tendineae rupture. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, claimant makes the same arguments she made in contest.⁸ In response, the Trust argues that the opinions of claimant's experts are mere conjecture and do not establish that Ms. Vang's chordae tendineae rupture occurred during surgery. In addition, the Trust contends that claimant's medical records establish that the surgeon who performed Ms. Vang's mitral valve replacement, R. Kent Jex, M.D., observed chordae tendineae rupture when he first visualized claimant's mitral valve. The Trust further asserts that although claimant obtained a statement from Dr. Jex in connection with her contest of the finding of mitral annular calcification, she did not obtain a statement from him explaining that Ms. Vang's chordae tendineae ruptured during, or as a result of, her mitral valve surgery. Finally, the Trust argues that, contrary to claimant's experts opinions, rupture of the chordae tendineae during surgery is unlikely and uncommon.

The Technical Advisor, Dr. Vigilante, reviewed claimant's medical records and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have chordae tendineae rupture. Specifically, Dr. Vigilante determined that:

8. Claimant also requests any handwritten notes of the auditing cardiologist as well as any prior versions of the certification provided by the auditing cardiologist. The Trust, however, provided the documentation required by the Audit Rules. See Audit Rule 22. Further, the Audit Rules specifically preclude the taking of discovery in the show cause process. See id. Rule 41.

I reviewed the Claimant's echocardiogram of January 16, 1997.... This was a below average quality study with the usual echocardiographic views obtained.... There was no obvious ruptured chordae tendineae seen but this could not be excluded....

....

Review of the surgeon's operative note of February 10, 1997 conclusively demonstrated the evidence of severe elongation of chordae with a few small ruptured chordae. These were found in association with a mildly dilated mitral annulus and prolapse of the anterior mitral leaflet. It is clear from the operative report that these findings were made prior to attempt at repair of the mitral valve. Thus, it is profoundly unlikely that these findings were caused by the surgery itself. These mitral valve findings on surgical examination are more accurate than the findings on a below average quality chest wall echocardiogram. Therefore, it has been shown that the Claimant had ruptured chordae tendineae prior to mitral valve surgery.

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.8. That is, there is conclusive medical evidence from surgical examination that the Claimant had ruptured chordae tendinae [sic] with comments as noted above.

In response to the Technical Advisor Report, claimant disagrees with the Technical Advisor based on the opinions of Dr. McLaurin and Dr. Levene.⁹

9. Claimant also argues that she is entitled to payment of Matrix A-1, Level IV benefits because the Trust did not comply with the deadlines established in the Audit Rules and Dr. Oliner's certification is incorrect and flawed because it included at least one incorrect date. None of the processing errors Ms. Vang alleges, even if true, would change our conclusion that there is no reasonable medical basis for her claim.

After reviewing the entire show cause record, we find claimant's arguments are without merit. As noted, the Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if there is evidence of certain identified medical conditions, including chordae tendineae rupture. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c).

In the present case, the operative report of claimant's mitral valve surgery states that claimant had chordae tendineae rupture:

Examination revealed a mildly dilated mitral annulus with prolapse of the anterior mitral leaflet and severe elongation of the chordae with a few small ruptured chordae. Attempt was made to replace these with Gore-Tex suture, but the exposure was very difficult on this obese lady and [I] was not happy with the result. I felt that her best option was mitral valve replacement with chordal preservation.

To avoid this plain text, claimant relies on opinions from her physicians, Dr. McLaurin and Dr. Levene, who opine that Ms. Vang's chordae tendineae rupture resulted from the surgery on her mitral valve. Such reliance, however, is misplaced because these opinions contradict the operative report, which clearly indicates that chordae tendineae rupture was found at the onset of claimant's surgery.¹⁰

10. For this reason as well, we reject claimant's assertion that the only way to determine whether she had chordae tendineae rupture prior to her mitral valve surgery is by reference to her pre-operative echocardiogram dated January 16, 1997.

Equally significant, neither Dr. McLaurin nor Dr. Levene performed claimant's mitral valve surgery. In addition, although claimant provided a verified statement of Dr. Jex as to the absence of mitral annular calcification during the contest phase, she did not submit a similar statement from Dr. Jex on the critical issue of chordae tendineae rupture. As such, claimant has not demonstrated that her chordae tendineae rupture was a result of her mitral valve surgery.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Vang did not have chordae tendineae rupture. Therefore, we will affirm the Trust's denial of Ms. Vang's claim for Matrix A benefits and the related derivative claim submitted by her spouse.